§170.315(a)(4) Drug-drug, drug-allergy interaction checks for CPOE

2015 Edition CCGs

Version 1.3 Updated on 05-08-2017

Revision History

Version #	Description of Change	Version Date
1.0	Initial Publication	10-22-2015
1.1	Added clarification that how the intervention is "indicated" to the user is at the discretion of the developer.	12-10-2015
1.2	Revised upon further analysis of the P&S Framework and the applicability of the "amendments" certification criterion (d)(4) to health IT capabilities that would not necessarily have any patient data for which a request for an amendment would be relevant.	04-24-2017
1.3	Removal of Amendments (§ 170.315(d)(4)) under Approach 1 in the Privacy and Security section of the table.	05-08-2017

Regulation Text

Regulation Text

§170.315 (a)(4) *Drug-drug, drug-allergy interaction checks for CPOE—*

(i) *Interventions.* Before a medication order is completed and acted upon during computerized provider order entry (CPOE), interventions must automatically indicate to a user drug-drug and drug-allergy contraindications based on a patient's medication list and medication allergy list.
(ii) *Adjustments.*
(A) Enable the severity level of interventions provided for drug-drug interaction checks to be adjusted.
(B) Limit the ability to adjust severity levels in at least one of these two ways:
(1) To a specific set of identified users.
(2) As a system administrative function.

Standard(s) Referenced
None

Certification Companion Guide: Drug-drug, drug-allergy interaction checks for CPOE

This Certification Companion Guide (CCG) is an informative document designed to assist with health IT product development. The CCG is not a substitute for the 2015 Edition final regulation. It extracts key portions of the rule's preamble and includes subsequent clarifying interpretations. To access the full context of regulatory intent please consult the 2015 Edition final rule or other included regulatory reference. The CCG is for public use and should not be sold or redistributed.

Link to Final Rule Preamble

Edition Comparision	Gap Certification Eligible	Base EHR Definition	In Scope for CEHRT Definition
Unchanged	Yes	Not Included	Yes

Certification Requirements

Privacy and Security: This certification criterion was adopted at § 170.315(a)(4). As a result, an ONC-ACB must ensure that a product presented for certification to a § 170.315(a) "paragraph (a)" criterion includes the privacy and security criteria (adopted in § 170.315(d)) within the overall scope of the certificate issued to the product.

- The privacy and security criteria (adopted in § 170.315(d)) do not need to be explicitly tested with this specific paragraph (a) criterion unless it is the only criterion for which certification is requested.
- As a general rule, a product presented for certification only needs to be presented once to each applicable privacy and security criterion (adopted in § 170.315(d)) so long as the health IT developer attests that such privacy and security capabilities apply to the full scope of capabilities included in the requested certification. However, exceptions exist for § 170.315(e)(1) "VDT" and (e)(2) "secure messaging," which are explicitly stated.

- Health IT presented for certification to this criterion (2015 Edition "drug-drug, drug-allergy interaction checks for CPOE") would not have to demonstrate the capabilities required by the 2015 Edition "amendments" certification criterion (§ 170.315(d)(4)), unless the health IT is presented for certification to another criterion that requires certification to the 2015 Edition "amendments" criterion under the privacy and security certification framework.

Table for Privacy and Security

- If choosing Approach 1:
  - Authentication, access control, and authorization (§ 170.315(d)(1))
  - Auditable events and tamper-resistance (§ 170.315(d)(2))
  - Audit reports (§ 170.315(d)(3))
  - Automatic access time-out (§ 170.315(d)(5))
  - Emergency access (§ 170.315(d)(6))
  - End-user device encryption (§ 170.315(d)(7))
- If choosing Approach 2:
  - For each applicable P&S certification criterion not certified for approach 1, the health IT developer may certify for the criterion using system documentation which provides a clear description of how the external services necessary to meet the P&S criteria would be deployed and used. Please see the 2015 Edition final rule correction notice at 80 FR 76870 for additional clarification.

Design and Performance: The following design and performance certification criteria (adopted in § 170.315(g)) must also be certified in order for the product to be certified.

- Safety-enhanced design (§ 170.315(g)(3)) must be explicitly demonstrated for this criterion.
- When a single quality management system (QMS) is used, the QMS only needs to be identified once. Otherwise, the QMS' need to be identified for every capability to which it was applied.
- When a single accessibility-centered design standard is used, the standard only needs to be identified once. Otherwise, the accessibility- centered design standards need to be identified for every capability to which they were applied; or, alternatively the developer must state that no accessibility-centered design was used.

Table for Design and Performance

- Safety-enhanced design (§ 170.315(g)(3))
- Quality management system (§ 170.315(g)(4))
- Accessibility-centered design (§ 170.315(g)(5))

Technical Explanations and Clarifications

Applies to entire criterion

Clarifications:

- There is no standard required for this certification criterion.
- The scope of this criterion is on the health IT system's ability to perform drug-drug, drug allergy interaction checks during CPOE. Certification to this criterion does not require the system to

perform drug-drug, drug-allergy interaction checks in other cases, such as when medications are reviewed or medication/medication allergy lists are updated. [see also 75 FR 44602; 77 FR 54206; 80 FR 62618]
- No standards are required for this criterion, but checks are only expected to be performed based upon structured data. [see also 75 FR 44602]
- For testing and certification purposes, drug-allergy contraindications include adverse reaction contraindications. [see also 77 FR 54208]
- This criterion is separate and distinct from the § 170.315(a)(9) clinical decision support criterion. [see also 77 FR 54208]
- How the interventions are automatically indicated to a user is at the discretion of the developer and they have the flexibility to implement this functionality based on their customer preferences and in line with their user-centered design requirements.

Paragraph (a)(4)(i)

Technical outcome – Interventions should automatically occur during CPOE and before the medication order is completed and acted on.

Clarifications:

- A Health IT Module is only expected to perform drug-drug, drug-allergy interaction checks based on medication and medication allergy information included in the system as structured data. The Health IT Module is not expected to be capable of reading or accessing information in non-structured formats (e.g., scanned documents, images) for this provision. [see also 75 FR 44602]

Paragraph (a)(4)(ii)(A)

Technical outcome – The health IT allows a user to adjust the level for drug-drug interaction interventions provided.

Clarifications:

- This functionality does not need to be provided to every user; testing and certification will ensure that the functionality exists for authorized users. [see also 77 FR 54208]
- This functionality only adjusts what may display to an end user. It does not change the severity level/clinical significance of an interaction or contraindication, but allows authorized users to tailor the interventions the users receive.

Paragraph (a)(4)(ii)(B)

Technical outcome – The ability to adjust drug-drug, drug-allergy interactions should be able to be limited to a defined set of users.

Clarifications:

- “Identified set of users” means that the technology must enable a provider to assign only certain users (e.g., specific providers, system administrator) with the ability to adjust severity levels for drug-drug, drug-allergy interaction interventions. [see also 77 FR 54208]

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